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**KM.**

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/448,042    11/23/99    LAPIDUS

S    EXT-023

021323    HM12/0411  
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EXAMINER

HOUTTEMAN, S

ART UNIT

PAPER NUMBER

1656

DATE MAILED:

04/11/01

**4.**

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/448,042

Applicant(s)

Lapidue et al.

Examiner

Scott Houtteman

Group Art Unit

1656



☐ Responsive to communication(s) filed on \_\_\_\_\_

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-23 \_\_\_\_\_ is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-23 \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

1. Claims 1-23 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 1-23 are indefinite in that the limitations “and comprising a donor molecule” and “and comprising an acceptor molecule” lack clear antecedent basis. It is not clear which specific claimed element actually “comprises” these donor and acceptor molecule. The words donor and acceptor appear to be reagents to be used in the method. Inexplicably, these limitations are placed in the middle of the two method steps “exposing . . . sample to . . . primer” and “performing . . . primer extension.” Accordingly, it is unclear where the reagents are located. The donor and acceptor molecules, could be with the biological sample, the primers etc. Amendment is suggested to recite the original location of the various reagents at the start of the method and the point in which these reagents are mixed.

B. Claims 2-23 are indefinite in the recitation “activates” in the context of a “donor” which “activates” a receptor. The terms “donor” and “acceptor” are unlimited by any molecular characteristics. Without molecular characterization, the nature of the claimed terms “activation” and “capable of interacting” are unclear.

C. Claims 20-23 are indefinite in the recitation of a method of “identifying” a “single nucleotide polymorphic variant.” One of the steps of the method requires that one already had identified the variant. The claims recite “a primer . . . capable of hybridizing . . . at a locus immediately 5’ to a single nucleotide polymorphic locus.” In order to design the claimed primer to bind at the claimed position, one must already have identified the variant. Thus, it is unclear

whether one "identifies" the variant using the method or if one has already "identified" the variant in order to use the method. In the later case, the intended result of the method is unclear. It could be to determine the presence of a variant in a sample. Amendment to clarify the purpose of the method is suggested.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

3. Claims 1-23 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Haff et al., US Pat. 5,885,775, 3/1999 (Haff) in view of Mathies et al. US Pat. 5,869,255, 2/1999 (Mathies).

Haff discloses exposing a biological sample to primers capable of hybridizing with a nucleic acid and performing primer extension with a nucleotide complementary to the target donor molecule

The claims differ from Haff in the recitation of “donor” and “acceptor” molecules, for example those donors and acceptors recited in claims 10-12. Mathies, however, discloses these donors and acceptors. See, for example, Mathies col. 5, lines 44-57.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the donors and acceptors of Mathies with the method of Haff for the reasons explicitly discloses in Mathies. Haff discloses a method of PCR. Mathies explicitly discloses that “improved methods . . . which allow for multiplexing of samples, so that a plurality of components can be determined in the same system and in a single run.” Mathies also suggest the use of donor and acceptor molecules because they provide for “a large Stokes shift of emission.” See Mathies col. 2, lines 1-36. The Stokes shift, a difference between the wavelength of absorbed light and emitted light, is useful because one can filter out the incoming absorbed light at the one wavelength but allow the emitted light to pass at the second, shifted wavelength.

4. Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Technology Center 1600 Fax numbers are (703) 305-3014 and 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott Houtteman whose telephone number is (703) 308-3885. The examiner can normally be reached on Tuesday-Friday from 8:30 AM - 5:00 PM. The examiner can also be reached on alternate Mondays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.

Scott Houtteman  
March 19, 2001

A handwritten signature in black ink, appearing to read "Scott W. Houtteman", with a stylized flourish at the end.

**SCOTT W. HOUTTEMAN  
PRIMARY EXAMINER**